# REMARKS

**Claim Rejections under 35 U.S.C. 112, First Paragraph, Written Description Requirement, New Matter**

The Examiner has rejected claims 1-8, 30-31 and 36-39 under 35 U.S.C 112, first paragraph, as failing to comply with the written description requirement. According to the Examiner, the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention.

The Applicants have amended claims 1, 30, 36 and 38 taking into account the Examiner's remarks and the following remarks. Claims 37 and 39 have been canceled.

The Applicants believe that the claims do contain subject matter that is described implicitly in the specification such that one skilled in the relevant art would understand the breadth of the claimed invention. Applicants requested the help of Dr Herbert Harris to analyze the data in the patent application and to show that the ranges covered in the amended claims are implied in Figures 3A and 7A. The data in these Figures were used to generate the data in Figures 3C and 7C. The CV of Dr Herbert Harris is included attached to the submitted declaration. Dr Harris is exemplary of a scientist skilled in the relevant art.

Dr Herbert Harris stated as followed:

> Basically, I took the 95% confidence boundaries around the 1 mg/kg points in Figures 3A and 7A and projected them onto a regression line that fit the data. From this I was able to calculate the mg/kg values that corresponded to the upper and lower 95% confidence bands. From the cumulative locomotor data (Figure 3C) I calculated a range of 0.8 -1.3 mg/kg. From the stereotypy data (Figure 7C), I calculated a range of 0.7-1.4 mg/kg.
>
> The calculations I used to get the dose ranges were based on data in the application. The 1 mg/kg points are included in Figures 3A and 7A that accompany the application. I used these points along with the error bars around them (also in the application) to construct confidence intervals and derive corresponding mg/kg doses.

This was relatively easy for me because I have a computer program (GraphPad) which allowed me to "open" the figures and extract the numerical data underlying the points and error bars. However, the data was already present in the original application. Additionally, a scientist could measure these numbers directly from the graphs.

The dosage ranges claimed in claims 1, 30, 36 and 38 reflect the data already presented in Figures 3A and 7A and reflect standard manipulations of data used by scientists in the laboratory. Therefore, determining these 95% confidence limits around the 1 mg/kg data points does not introduce new matter. The Applicants request that these claims be allowed.

**Claim Rejections under 35 U.S.C. 103**

The Examiner has rejected claims 1-8, 30-31, 36 and 38 under 35 U.S.C 103(a) as being unpatentable over the Salvesen et al. reference in light of STN Registry File No. 17590-01-1 and Stedman's Medical Dictionary (Twenty-Second Edition, 1972; p.377) each cited to show facts, in view of Remington's Pharmaceutical Sciences (Sixteenth Edition, 1980; ppp.420-426).

The amendments to the dosages in claims 1, 30, 36 and 38 merely reflect the 95% confidence limits around the 1 mg/kg data points and are dosages where the unexpected results of the claimed invention would be expected to be observed. The declaration of Herbert Harris, Ph.D. is provided for support of Applicants' position that it is expected that these dosage ranges would show more activity and fewer side effects versus other dosages as shown specifically for the 1 mg/kg dose.

The Examiner further states that the claims should be restricted to the particular vehicle (100% DMSO) used in the examples and purportedly used to elicit the unexpected results. However, as stated in Dr. Harris' declaration, DMSO is a commonly used diluent in preclinical studies and is inert. It is replaceable with any of a number of diluents, such as those described in the specification and in no way would affect the unexpected results observed.

In view of the above, Applicants do not believe the Salvesen reference predicts, teaches, suggests or motivates the present invention either in light of STN Registry File No. 17590-01-1 which shows the structure of amphetaminil and or in light of Stedman's Medical Dictionary which shows that dragees are sugar-coated pills or capsules, or in light of Remington's Pharmaceutical Sciences which shows that drugs are chemically modified to alter the duration of action of a drug; to modify the transportation and distribution of the drug in the body; to reduce toxicity; and to

overcome difficulties encountered in pharmaceutical formulation procedures or in the dosage form itself.

Applicants believe that the claimed invention is patentably distinct from the references cited by the Examiner and that the foregoing remarks place the claims in condition for allowance. No new matter has been introduced by these amendments.

Any questions about this response should be addressed to Karen Guerrero. The telephone number is 610-933-2490.

Sincerely,
/Karen Guerrero/

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